

COMPARATIVE STUDY BETWEEN PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL IN ADULT PATIENTS UNDERGOING ELECTIVE SURGERY UNDER GENERAL ANAESTHESIA: A RANDOMISED TRIAL

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Abstract

Background: Supraglottic airway devices are used for anesthesia in elective surgical procedures circumventing the need for intubation. The I-gel airway is a new supraglottic airway device without an inflatable cuff. The Proseal LMA is a second generation supraglottic airway device with modified cuff and a drainage tube. The present randomized, prospective study was conducted to compare the efficacy of the I-gel airway with the Proseal laryngeal mask airway (P-LMA) in adult patient undergoing elective surgery under general anesthesia. **Materials and Methods:** The study was done among the study participants scheduled for general and gynaecological surgery under general anesthesia in Government Thanjavur Medical College by the Department of Anesthesiology. The study was done for a period from August 2022 to July 2023. Sixty study participants recruited based on inclusion and exclusion criteria. The enrolled study participants were randomized and allocated into two groups (30 each). Group P-Proseal laryngeal mask airway and in Group I- I-gel was inserted. Baseline characteristics of the study participants were obtained. Duration of insertion, attempts of insertion, ease of insertion, hemodynamic changes to insertion, oropharyngeal seal pressure and post-operative airway complication are compared between two groups. Data collected were entered in MS Excel and the statistical analysis was done in SPSS 23.p value <0.05 is considered as statistically significant. **Result:** Time taken for successful insertion was significantly less in I-gel group 13.23±3.31 seconds and Proseal LMA- 23.63±4.53 seconds p<0.001. The numbers of insertion attempts were also less with i-gel group. The Oropharyngeal seal pressure in Proseal LMA group was significantly higher than I-gel group (mean±SD: 30.16±3.37 vs 27.19±2.43 cm of H₂O; p<0.001). **Conclusion:** Our study concluded stating that both the supraglottic airway devices can be used safely during general anesthesia under controlled ventilation. When comparing both the devices P-LMA provides better sealing pressure but takes longer time to insert than I-gel.

INTRODUCTION

The gold standard airway device was the endotracheal tube. But laryngoscopy and endotracheal intubation always associated with certain morbidities ranging from minor to serious i.e from sore throat to autonomic stimulation and failed intubation. Supraglottic devices are suitable for emergency airway procedures and routine anaesthesia.^[1] Supraglottic airways (SGAs) have advantages over them like maintaining the

hemodynamic stability, increased speed and ease of placement.^[2,3] I gel airway and the Proseal LMA are second generation supraglottic airways reduces the risk of aspiration and provides the good pharyngeal seal which makes the performance efficient and reliable. This study aims to compare duration of insertion, attempts of insertion, ease of insertion, hemodynamic changes to insertion, oropharyngeal seal pressure and post-operative airway complication.

MATERIALS AND METHODS

Study Setting: This study was conducted among the study participants scheduled for general and gynecological surgery under general anesthesia in Government Thanjavur Medical College Hospital, Thanjavur by the Department of Anesthesiology. The study was done for a period from August 2022 to July 2023.

Study Design: Randomized controlled study

Sample Size: The study participants fulfilling the inclusion and the exclusion criteria were included in the study throughout the study period. The final attained sample is 60. The study participants were grouped into two groups (30 each). Group P- P-LMA, Group I - I-gel.

Inclusion Criteria

Elective surgeries under general anaesthesia

- Age 18-60 years and both sexes
- ASA grade I and II

Exclusion Criteria

- ASA III and IV
- Age less than 18 years and more than 60 years
- Mallampatii Grade III and above
- Emergency surgeries
- Head and neck surgeries
- Patients with decreased mouth opening
- BMI >28 kg/m²
- Increased risk of aspiration and decreased lung compliance
- Patient with abnormal and distorted anatomy of pharynx and obstructed airway beyond larynx.

Data Collection Method: After obtaining the Institutional Ethical Committee clearance, the study was started after obtaining patients informed consent. The study participants recruited during the study period i.e 60 will undergo the routine investigations and then the preanesthetic fitness. Injection Glycopyrrolate 0.2 mg and Injection Fentanyl 2 mcg /Kg was given as premedication intravenously. The study participants were induced with Injection Propofol 2 mg/Kg and Injection Succinylcholine 2 mg/Kg. Supraglottic airway device was inserted according to the allotted group as per manufacturers standard protocol according to their weight. Maintenance was achieved by oxygen 33%, nitrous

oxide 66 % and sevoflurane 1-2 %. Once the effect of succinylcholine was over loading dose of intravenous atracurium 0.5 mg/kg followed by intermittent dose of 0.1 mg/kg was given when required. The expiratory valve was closed and fresh gas flow of oxygen 3 litres was kept. Stethoscope was kept in front of mouth and positive pressure ventilation was given. The manometer of the closed circuit pressure is noted when the audible sound was heard. The pressure was taken as the corresponding device oropharyngeal sealing pressure Duration of insertion was measured from the time the facemask was taken away from the face until successful ventilation of the patient. Ease of insertion was defined as correct placement of device in sniffing position without any requirement of airway manipulation like chin lift, jaw thrust, head extension and neck flexion.. The number of insertion attempts along with airway manipulation required for correct placement was recorded. At the end of surgical procedure anaesthesia was discontinued, the effect of non-depolarizing muscle relaxant in the patient was reversed with inj. Neostigmine 60 µg/kg and inj. Glycopyrrolate 10 µg/kg. The device was removed after recovery of the patient from anaesthesia and muscle relaxant. Blood staining of the device, dental trauma, hoarseness of voice, sore throat, laryngospasm were noted. Standard protocol was followed in recovery, postoperative monitoring and postoperative analgesia.

Statistical analysis: The obtained data was entered in MS Excel Windows 10. Statistical analysis was done with the help of SPSS 23. Continuous data was expressed in terms of mean and standard deviation. Categorical data was expressed in terms of Numbers and Percentages. Test of association for Categorical data was Chi square test and for Continuous data was t test and Anova test. p values <0.05 is considered as statistically significant.

RESULTS

Both the groups were comparable in terms of their demographic characteristics (age, weight, height and gender) There was no significant difference in demographic data in the two groups [Table 1].

Table 1: Demographic profile of the study participants

Baseline characteristics	P-LMA	I-gel	P value
Age			
<30 years	8(26.7%)	15(50%)	.176
31-40 years	15(50%)	10(33.3%)	
>40 years	7(23.3%)	5(16.7%)	
Sex			0.50
Male	24(80%)	24(80%)	
Female	6(20%)	6(20%)	
Weight distribution			0.001*
<50 Kg	13(43.3%)	1(3.3%)	
>50 Kg	17(56.7%)	29(96.7%)	
Height distribution			0.01*
<150 cm	14(46.7%)	6(20%)	
>160 cm	16(53.3%)	24(80%)	

Table 2: Comparison between I-gel and P-LMA groups with respect to different parameters

Variables	P-LMA	I-gel	P value
Insertion Attempts First Attempt Second Attempt	25(83%) 5(17%)	28(93%) 2(7%)	0.11
Ease of Insertion Easy Difficult	21(70%) 9(30%)	27(90%) 3(10%)	0.02*
Duration of Insertion <15 second 16-30 second >31 second	4(13.3%) 22(73.4%) 4(13.3%)	19(63.3%) 9(30%) 2(6.7%)	0.003*
Mean Insertion Time(seconds)	23.63±4.53	13.23±3.31	<0.001*
Oropharyngeal sealing Pressure (cm H2O)	30.16±3.37	27.19±2.43	0.002*

Table 3: Comparison of systolic and diastolic BP between the two groups

Insertion	Systolic BP		P value	Diastolic BP		P value
	P-LMA	I-gel		P-LMA	I-gel	
Before insertion	121.66±11.86	120.13±7.77	0.55	73.03±8.00	72.5±5.07	0.76
During	126.5±8.53	129.7±7.79	0.13	74.73±4.55	77.63±6.28	0.04*
After	122.167±7.93	123.5±8.62	0.53	72.6±4.20	74.13±5.24	0.21
Intraop	117.2±7.93	117.43±7.59	0.90	74.16±4.20	75.26±4.35	0.32
Removal	126.83±9.21	125.63±7.79	0.58	74.73±4.55	75.73±4.35	0.38
After removal	114.8±8.27	118.06±6.48	0.09	74.86±6.18	75.53±3.92	0.61

Table 4: Comparison of Heart and SPO2 between the two groups

Insertion	Heart rate		P value	SPO2		P value
	P-LMA	I-gel		P-LMA	I-gel	
Before insertion	96.8±8.40	94.9±8.09	0.37	98.4±0.50	98.13±0.68	0.08
During	95.26±7.21	96.43±6.95	0.52	99.7±0.58	99.67±0.87	0.87
After	88.3±5.41	89.3±7.91	0.56	99.6±0.67	99.7±0.46	0.50
Intraop	88.3±5.41	86.7±7.25	0.40	99.6±0.67	99.6±0.89	0.99
Removal	87.6±6.37	86.33±8.99	0.53	99.56±0.67	99.2±0.89	0.08
After removal	86.9±6.71	87.33±6.04	0.79	99.1±0.62	98.9±0.57	0.19

Table 5: Complication after removal of device

Variables	P-LMA	I-gel	P value
Presence of blood on airway device	2(6.7%)	1(3.3%)	0.27
Lip or dental injury	0(0%)	0(0%)	NA
Laryngeal spasm	0(0%)	0(0%)	NA
Sore throat	0(0%)	0(0%)	NA
Postoperative nausea or vomiting	1(3.3%)	1(3.3%)	0.5
Hoarseness of voice	0(0%)	0(0%)	NA

[Table 2] shows that insertion and ventilation was possible at the first attempt in 93% of patients in the I-gel group and in 83% in P-LMA group. The mean duration of insertion attempts was 13.23±3.31 seconds in I-gel group, while it was 23.63 ± 4.53 seconds in P-LMA group.

The difference between both groups regarding duration of insertion attempts was statistically significant (P =0.03), while the number of insertion attempts was statistically insignificant between both the study groups (P >0.05). There were no failures in insertion of supraglottic airway devices in any group. The Oropharyngeal sealing Pressure was 27.19±2.43 and 30.16±3.37cm of H2O for the I-gel and P-LMA groups respectively, which was statistically significant (p < 0.01).

No statistically significant difference was found between both groups of the study, regarding each of systolic BP, diastolic BP, heart rate, SPO2 (%) throughout the whole duration of the surgery [Table 3&4]. There was no incidence of desaturation, sore throat, dental trauma or laryngospasm [Table 5]. However, blood staining of P-LMA and I-Gel was

noted in 1 patient and postoperative nausea vomiting was seen in 1 patient of P-LMA and I-gel statistically insignificant.

DISCUSSION

Supraglottic airway devices have revolutionized anaesthesia practice and are now increasingly being used as an excellent alternative to mask ventilation and tracheal intubation with least complications. The I gel is a disposable SGA which is made up of soft, thermoplastic elastomer like gel with a non inflammable cuff. It is easier and faster to insert than the other SGA's. It has a flattened stem with a rigid bite block what acts as a buccal stabilizer which reduces the axial rotation and mal positioning and a port for the gastric tube insertion. It is latex free device and so does not require a digital insertion into patients mouth.^[6,7]

The ProSeal laryngeal mask (P-LMA) is with a modifiable cuff made of silicone with a double tube arrangement. It is a reusable SGA.^[9] The posterior inflatable cuff increases the pharyngeal seal. Due to

the larger bulk of the P-LMA tip and the back plate absence on the device and poor insertion technique results in the posterior folding of the device.^[9]

Both the groups were comparable in terms of their demographic characteristics (age, weight, and gender). Device insertion was successful in all patients, 83% first attempt in P-LMA group and 93% in I-gel group was achieved which was similar to another study by Iswar singh et al,^[10] and in contrast to the results of Park SK et al,^[9] study where the high rate of insertion success on first attempt was obtained in both I-gel group and P-LMA group. We found that the ease of insertion was more with the I-gel supraglottic airway compared with P-LMA and statistically significant consistent with results of Chauhan G et al.^[11] In our study, the mean heart rate, systolic, diastolic, mean arterial blood pressure and Spo2 in P-LMA- and I-Gel group were observed at base line, before insertion, immediately after insertion, removal and after removal found that there was no statistical significant difference between two groups. Our observations are also consistent with results of Shin WJ et al.^[12] The difference in the oropharyngeal seal pressure between I-gel airway and P-LMA was statistically significant in our study ($p < 0.001$) was similar to study done by Van Zundert et al and Mukadder et al.^[13,14]

CONCLUSION

From our study we concluded that both the supraglottic airway devices can be used safely during general anaesthesia. I-gel is better than P-LMA in terms of lesser insertion time, ease of insertion and higher first attempt success rate. The P-LMA airway provides a better oropharyngeal sealing pressure compared to I-gel.

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